

REMARKS

The pending final Office Action addresses claims 1-33, all of which are rejected.

Rejections Pursuant to 35 U.S.C. §102

Claims 1-5, 9-10, 21-23, and 28-30 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,928,693 of Goodin et al.

Claim 1 is directed to a pressure sensor device including an elongate catheter having a first lumen adapted to accommodate fluid flow therethrough. A second, separate, fluid-filled, fluid-impermeable, sealed lumen is filled with an incompressible fluid and extends between a pressure-sensitive component adapted to be exposed to an external pressure source, and a pressure sensor that is effective to measure pressure of the external pressure source in response to displacement of the pressure-sensitive component. Similarly, independent claim 22 recites a pressure sensor coupled to a flexible membrane disposed at a distal end of the catheter and adapted to respond to intra-ventricular pressure changes, and claim 29 recites a pressure-sensitive member adapted to respond to pressure changes and pressure sensor adapted to measure the pressure changes.

Goodin cannot anticipate the claimed invention as it does not enable a person skilled in the art to make or use a blood pressure monitoring catheter. Specifically, Goodin lacks an enabling disclosure in as much as it fails to teach a pressure-sensitive component or flexible membrane adapted to be exposed to or to respond to an external pressure source, and a pressure sensor that is effective to measure pressure of the external pressure source.

A claimed invention cannot be anticipated by a prior art reference if the cited prior art is not enabled. *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). For a disclosure to meet the enablement requirement established in 35 U.S.C. §112, the claimed invention must be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir.

1988). As described below, Goodin does not enable one skilled in the art to take measurements of the pressure of blood using the device described therein.

Figure 1 of Goodin illustrates a bi-lumen blood pressure monitoring catheter (10) with one of the lumens (20) filled with an incompressible fluid, such as saline. Goodin does not discuss in detail how the incompressible fluid is used to measure pressure. Goodin merely states that the pressure is transmitted through the fluid to a blood pressure monitoring component. While the Examiner states that element 14 of Goodin is a pressure-sensitive component, element 14 is merely the distal end of the catheter. Goodin does not illustrate or describe the pressure-sensitive component or the flexible membrane, and thus the configuration of the component is unknown. Although not shown, the Examiner also argues that a pressure sensor is located at the proximal end of the catheter, as Goodin states that blood pressure measuring equipment is located near the proximal end of the catheter (see Column 4, lines 23-24). While Goodin makes a general allusion to equipment for measuring pressure, there is no teaching in Goodin about what this equipment might be. Thus, Goodin lacks the pressure-sensitive component or flexible membrane and the pressure sensor required by claims 1, 22, and 29, and therefore Goodin is not enabling and cannot anticipate the claimed invention.

Accordingly, independent claims 1, 22, and 29, as well as claims 2-5, 9-10, 21, 23, 18, and 30 which depend therefrom, distinguish over Goodin and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. §103

(1) Claim 6

Claim 6 is rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Goodin in view of U.S. Patent No. 5,573,007 of Bobo Sr. The Examiner argues that Goodin discloses the claimed invention, but admits that Goodin fails to teach the use of a flexible membrane disposed across an opening in the sidewall for fluid entry. Thus, the Examiner relies on Bobo to teach a pressure monitoring catheter having a membrane disposed across an opening formed in a sidewall, arguing that it

would have been obvious to modify Goodin with a flexible membrane of Bobo to provide a more accurate pressure sensing catheter.

As noted above, Goodin cannot anticipate claim 1 because Goodin is not enabling. Claim 6 depends from claim 1 and is therefore allowable at least because claim 1 is allowable. Claim 6 further distinguishes over Goodin and Bobo because no person having ordinary skill in the art would be motivated to modify Goodin in view of Bobo to include a flexible membrane disposed across an opening in a sidewall of the catheter. The Examiner merely states that it would have been obvious to make the modification to provide “a more accurate pressure sensing catheter.” Since Goodin states that the pressure is transmitted through the fluid to a blood pressure monitoring component and does not disclose the use of any type of flexible membrane for receiving pressure, it is unclear exactly how the fluid of Goodin functions. Thus, it is unclear whether there is a need to provide “a more accurate pressure sending catheter.” The Examiner has failed to establish a prima facie case of obviousness.

Accordingly, claim 6 distinguishes over Goodin and Bobo and represents allowable subject matter.

(2) Claims 7, 8, 11-20, 25-27, 31-33

Claims 7, 8, 11-20, 25-27, and 31-33 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goodin in view of various references set forth in the Office Action. The Examiner relies on these references to teach various features recited in the dependent claims and not taught by Goodin. As indicated above, Goodin is not enabling as to a pressure-sensitive component or flexible membrane and a pressure sensor, and therefore Goodin cannot anticipate the claimed invention. The various secondary references cited by the Examiner do not remedy these deficiencies of Goodin. Accordingly, claims 7, 8, 11-20, 25-27, and 31-33 distinguish over Goodin and the various secondary references and represent allowable subject matter.

(3) Claims 24 and 30

Claims 24 and 30 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Goodin in view of U.S. Patent No. 5,573,007 of Bobo, Sr. The Examiner relies on Bobo to teach various features not taught by Goodin. As noted above, Goodin cannot anticipate claims 22 and 29 because Goodin is not enabling. Claims 24 and 30 depend from claim 22 and 29 and are therefore allowable at least because claims 22 and 29 are allowable. Further, the Examiner has failed to establish a prima facie case of obviousness, as noted above, with regard to Goodin and Bobo. Accordingly, claims 24 and 30 distinguish over Goodin and Bobo and represents allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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